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VIA EMAIL

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Hon. Thomas I. Vanaskie (Ret.)

Special Master

Stevens & Lee

1500 Market St., East Tower, Suite 1800

Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***
Case No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Please accept this letter on behalf of the Plaintiffs as an update on unresolved discovery disputes.

1. ZHP

A. *Chinese State Secrets*

On March 30, 2021, Plaintiffs raised four issues based on their meet and confer with ZHP the prior Friday, March 26, 2021. The hope was that in combination with Plaintiffs' agreements not to challenge a number of documents during the meet and confer, ZHP's cooperation on the four issues would serve to drastically narrow the issues in dispute. Unfortunately, it appears that ZHP was content to have Plaintiffs drop challenges but not to make any concrete effort on its part

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to narrow the remaining issues. On March 31, 2021, ZHP told the Court that it would address those issues promptly, but that has not happened. ZHP's April 1, 2021 letter only addressed the first issue regarding its assessment of which documents were or were not duplicative of one other.

The three remaining issues are:

- (1) Many of the documents contain factual information provided by ZHP, in many cases concerning ZHP's investigation into the nitrosamine contamination of valsartan, and Plaintiffs have a right to know that information, and ZHP agreed to review those documents to determine whether they could be produced in redacted form;
- (2) A large number of the documents concerned reports of non-Chinese regulatory investigations and actions, and this information cannot possibly be a Chinese state secret. ZHP agreed to consider producing these documents in whole or in part; and
- (3) The logs also contain documents reporting allegedly false information contained on the internet to the Chinese government, and to the extent that information is already on the internet, it cannot be a Chinese state secret.

Plaintiffs ask the Court to order ZHP to identify the documents that contain the foregoing issues, and to take a position as to what further steps ZHP is willing to take. Upon receipt of that update, Plaintiffs will be prepared to file a motion to compel production of some or all of the remaining documents on the logs.

B. Privilege Challenges:

Plaintiffs sent email correspondence to ZHP on March 6 and 18, 2021 challenging the privilege designations of specific documents and categories of documents. At the time of this writing, the ZHP Defendants have failed to respond to the challenges.

With respect to categories of documents improperly withheld, Plaintiffs have observed many instances where entirety of emails and attachments have been withheld, when it is obvious that some portion of the email is not privileged. The law is clear that underlying facts contained in documents are never privileged. *In re Human Tissue Prod. Liab. Litig.*, 255 F.R.D. 151, 164

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(D.N.J. 2008). Indeed, the ESI Protocol dictates that in a situation where “all lesser-contained e-mails are not independently privileged, *the topmost email thread must be redacted rather than withheld.*” D.E. 127 at p. 17 (emphasis added).

ZHP also appears to be classifying entries on its privilege log as “attorney-client communications,” when they appear to be drafts of documents created during the ordinary course of business. Attorney-work product is only privileged if prepared in anticipation of litigation. *Conoco, Inc. v. U.S. Dept. of Justice*, 687 F.2d 724, 730 (3d Cir.1982). Moreover, to constitute as attorney work-product, the material at issue must have been produced because of the prospect of litigation and for no other reason. *Id.* Examples of documents which appear to be improperly withheld on this basis are as follows:

- CTRL00000669
- CTRL00000670
- CTRL00000761

At time, ZHP also claims these draft documents have been prepared “in anticipation of litigation regarding regulatory issues.” These documents appear to span many years, beginning as early as 2011 and continuing until 2017. ZHP cannot credibly argue they were anticipating some unspecified litigation for that length of time. Either a lawsuit was eventually filed, or it was not. As such, Plaintiffs ask that ZHP identify, with specificity and case information, the litigation to which they refer when they reference “litigation regarding regulatory issues” on their privilege log. Plaintiffs must have this information to properly assess the veracity of ZHP’s work-product claim.

ZHP has also withheld a series of documents created from 2015-2017 on the basis these documents are “confidential information needed to render legal advice with Alan Klein regarding compliance issues.” On the face of ZHP’s own description these documents are neither include

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attorney-client communications, nor are they work-product prepared in anticipation of litigation. ZHP cannot withhold underlying factual information simply because that underlying factual information was provided to an attorney during the ordinary course of business. These documents include:

- CTRL00001505
- CTRL00001511
- CTRL00001516
- CTRL00001517
- CTRL00001504
- CTRL00001506
- CTRL00001508
- CTRL00001509
- CTRL00001510
- CTRL00001512
- CTRL00001513
- CTRL00001515
- CTRL00001518
- CTRL00001519
- CTRL00001520
- CTRL00001522
- CTRL00001526
- CTRL00001179
- CTRL00001523
- CTRL00000378
- CTRL00001530

Plaintiffs have also identified the following documents which appear to be improperly withheld:

- CTRL00001489-CTRL0000190: This document, an email with an attachment sent on September 12, 2014 to only non-legal Princeton employees, is described as an “email reflecting confidential attorney-client communications with Vincent Capuano regarding compliance issues.”
 - On the face of the entry, there are no attorneys participating in this communication. As such, it strains credulity that the entirety of the email contains attorney-client communications. Even if, *arguendo*, some of the email conveys attorney client communications, Plaintiffs are entitled to receive a redaction version of the document for all parts of the email that are not attorney-client communication.

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- As to the attachment to the email, (titled “Notice Letter”), ZHP has not identified any litigation to which this document was prepared. Moreover, around September 2014, Princeton was responding to a deficiency letter from the FDA regarding ZHP’s practice of releasing API with reduced testing results. It appears as though the withheld family includes a draft response to this deficiency letter. It cannot be disputed that Plaintiffs are entitled to each and every draft of this ultimate response, and any documents related to this response. ZHP is only entitled to withhold attorney work product if it is prepared in the anticipation of litigation. Litigation was not reasonably anticipated at this time.
- CTRL00001077: This document, a word document titled, “ClarusONE - Solco Sourcing Framework Agreement (03-OCT-17).pdf” was authored on November 9, 2017. ZHP Claims this document is an “agreement prepared in the course of litigation regarding pending litigation.”
 - However, this document was actually authored on November 9, 2017. Litigation was not pending, or even reasonably foreseeable at that time. Plaintiffs are entitled to production of this contract.
- CTRL00001084: This Document, an email sent on July 27, 2018 to only non-legal Princeton employees, is described as an “email reflecting confidential attorney-client communications with Alan Klein regarding regulatory issues.” The email appears to be a forward of an email that says FDA latest release.
 - On the face of the entry, there are no attorneys participating in this communication. Moreover, the entry appears to forward information regarding an FDA release. Plaintiffs are entitled to receive any underlying facts contained in the email (including the underlying facts of what the FDA was saying).
- CTRL00001065, CTRL00001065, CTRL0000106: This series of withheld emails were sent on August 16, 2018 and August 17, 2018, and bear the subject line “Another incorrect Valsartan article.”
 - On the fact of the entry, the email appears to be about a published article, which is not privileged at all. Plaintiffs are entitled to all underlying facts contained in this email.
- CTRL00001068, CTRL00001069-70: This series of withheld emails were sent on August 15, 2018, and bear the subject line “Bloomberg Article”
 - On the face of the entry, the email appears to be about a published Bloomberg Article, which is not privilege at all. Plaintiffs are entitled to all underlying facts contained within this email.

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- CTRL00001496: This is a PDF document titled “FDA Recall News 2018-07-27” which is being withheld as work-product on the basis of “Press release forwarding information collected in anticipation of litigation regarding customer relations.”
 - Work-Product privilege does not apply to public information without more. The entry for the item does not appear to include any impressions or notations of any attorney.

As Plaintiffs’ review of the ZHP entities privilege logs continues, Plaintiffs anticipate that the above list is not exhaustive of all privilege challenges Plaintiffs will make as preparations for depositions continue.

C. ZHP’s Motion for a Protective Order

The Court is currently considering ZHP’s motion for a protective order. Plaintiffs await the Court’s decision in order to continue assessing the propriety of ZHP’s extensive confidentiality designations.

2. Hetero

Since the status conference on March 31, 2021, Hetero has made no additional productions nor provided any additional responses. Plaintiffs are concerned that no additional documents have been produced, nor has Hetero updated Plaintiffs on their status.

As outlined in a letter sent to Hetero on March 29, 2021, Hetero is still missing key versions of numerous quality system manuals, SOPs, site master files, Master SOP indexes, and testing documents, despite multiple supplemental productions.

Further, Hetero still has not produced documents related to the drafting, editing, modification, distribution, and implementation of any of the quality systems manuals, testing documents, and SOPs Hetero has produced. Hetero states that when revisions are proposed for an SOP by a department within each Unit, the QA department for the Unit places the SOP in a shared folder, and then edits and revisions are made to the SOP until finalized, then a paper copy is

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circulated to the heads of stakeholder departments for any further edits, and then a master copy is signed. Plaintiffs have not received any documents evidencing a request for revisions, nor any draft versions of SOPs either during the electronic or manual editing process. Similarly, Plaintiffs have not received any revision requests or drafts of the quality systems manuals and testing documents.

Hetero still has not produced a list of the applications, databases, sharepoints, and other central document and data locations that contained the relevant documents and data, despite its agreement to do so weeks ago. It has only described in very general terms that each Unit has their own de-centralized server, but that is not enough. For example, Hetero has not identified the types of equipment and software used to conduct testing, nor how that testing data is stored or kept, and what was done to retrieve and produce such data. Judge Schneider required each set of manufacturer and finished dose defendants sit for an approximately two-hour in-person ESI interview back in November 2019 in order to determine this type of information. Hetero's India entities, however, did not provide information at that time because they had not appeared in the litigation due to the time delays related to Hague service, and Hetero's USA entities that did appear claimed to have no information concerning Hetero's India entities. Unfortunately, that lack of participation has led to significantly incomplete data regarding Hetero's document policies and sources of data. Plaintiffs request that Hetero now fully answer the questions that were posed to defendants during that interview.

Last week, just before the status conference, Hetero produced what it identified as batch records and certificates of analysis, which are categories of documents that should have been produced months ago. While Plaintiffs appreciate Hetero's production of these additional documents, this further adds to Plaintiffs' concern that Hetero's production has been incomplete.

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Hetero stated in its letter that it discovered “that all Batch records were not produced” in Hetero’s ESI production, and then adds “[a]lthough Plaintiffs have not raised this concern, in the interest of full disclosure. . . intend to produce same to Plaintiffs.” Plaintiffs are concerned at this statement, because *how were Plaintiffs to know that these batch records were missing in order to raise this as a concern?* There was no way for Plaintiffs to have known Hetero’s production of batch records was incomplete in order to raise it as an issue. Thus, it raises the question, *are there other sets of documents that are either incomplete, or entire categories of relevant documents that have not been produced that Plaintiffs do not even know about?*

As Plaintiffs review the documents Hetero has now produced, we are finding evidence of more documents that are clearly relevant, and clearly missing. For example, as Plaintiffs have now discovered, Hetero was supposed to have conducted internal audits either every three months or every year, depending on the specific audit, and that presentations were made with regard to internal audits. However, Plaintiffs have only been able to locate a total of three internal audits, and no presentations concerning audits. These are documents that are clearly responsive to Plaintiffs’ document requests, yet Plaintiffs are only discovering even their existence now as a result of Hetero’s production. This pattern of Hetero failing to produce responsive documents, or even entire categories of responsive documents, unless specifically found as missing and identified to Hetero by Plaintiffs has been playing out for months now. This is of enormous concern as it is certain that Plaintiffs are incapable of identifying all missing documents due to the fact that they do not know the full extent of what exists, as evidenced by the production of missing batch records. It is not Plaintiffs’ responsibility to specifically identify individual responsive documents, it is Hetero’s responsibility to properly and fully respond to Plaintiffs’ document requests. Hetero clearly has not done so.

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Finally, as noted last week, it also now appears that some custodians and witnesses were never issued litigation holds, including Venkata Pravin Kumar Penubaka, Panchakshari Nanyappa Gowda; Dr. B.V. Ramireddy, Yogeswar Reddy Mamilla, Mohan Reddy Chilukurri, Bandaru Venkata Ramarao ("B.V. Ramarao"), and Dr. Murali Nagabelli, all of whom are expected deponents.

Hetero's production continues to be deficient, and has significantly prejudiced Plaintiffs' ability to proceed with depositions related to Hetero, which have now been postponed multiple times.

3. Aurobindo

Plaintiffs await the Court's rulings on the ToxRox and Meridan privilege log.

4. Mylan

Plaintiffs are prepared for the April 7, 2021 conference addressing Mylan improper withholding of approximately 4,200 documents.

Thank you for your consideration.

Respectfully,



Adam M. Slater

Cc: